510(k) Summary

JUN 29 2009

This 510(k) summary is prepared in accordance with 21 CFR 807.92.

General Information

Trade Name	**MR Cardiac Function Analysis**
Common Name	Picture Archiving and Communications System (PACS)
Classification Name	System, Image Processing, Radiological (21 CFR § 892.2050 - LLZ)

Applicant: **Ziosoft, Inc.**
1000 Bridge Parkway, Ste. 100
Redwood City, CA 94065
Tel 650-413-1300
Fax 650-596-7319

Contact: Richard Ball
Director, Regulatory and Quality Affairs

Intended Use

MR Cardiac Function Analysis

The MR Cardiac Function Analysis software option for use with Ziostation is intended for non-invasive post-processing of DICOM compliant cardiac MR images to semi-automatically calculate and display various functional parameters, such as left ventricular ejection fraction, end diastolic volume, end systolic volume, stroke volume, cardiac output, cardiac index, wall thickness, wall thickness ratio and regional wall motion display. These measurements can be used to assist the clinician in a cardiac evaluation.

Predicate Device

Ziosoft tool	Manufacturer of Predicate Device	Device Name	510(k) Number
MR Cardiac Function Analysis	Medis *Medical Imaging Systems B.V.*	MRI-FLOW Analytical Software Package (a.k.a. QMassMR)	K994282

Device Description

MR Cardiac Function Analysis is an add-on software package designed to be used with the basic Ziostation image management system to further aid clinicians in their analysis of anatomy and pathology. Universal functions such as data retrieval, storage, management, querying and listing, and output are handled by the basic Ziostation software. The additional capabilities provided by this new device are:

MR Cardiac Function Analysis software post-processes ECG-gated cardiac MR images and extracts the following left ventricular parameters from multi-phase data.

- Left ventricular ejection fraction
- End diastolic volume
- End systolic volume
- Stroke volume
- Cardiac output
- Cardiac Index
- Wall thickness
- Wall thickness ratio
- Wall movement
- Volume Curve
- Peak Ejection Rate
- Peak Filling Rate

Materials

The MR Cardiac Function Analysis tool consists entirely of software. No materials are contained in this product.

Testing Summary

The MR Cardiac Function Analysis software package will successfully complete integration testing/verification testing prior to Beta validation. Software Beta testing/validation will be successfully completed prior to release. In addition, potential hazards have been addressed by the Ziosoft Risk Management process.

Summary of Substantial Equivalence

MR Cardiac Function Analysis is substantially equivalent in intended use and function to the predicate device and other devices already marketed in the US.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2009

Mr. Richard Ball
Director, RA/QA
Ziosoft, Inc.
1000 Bridge Parkway, Suite 100
REDWOOD CITY CA 94065

Re: K091262
Trade/Device Name: MR Cardiac Function Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 28, 2009
Received: April 29, 2009

Dear Mr. Ball:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091262

Device Name: MR Cardiac Function Analysis

Indications for Use:

MR Cardiac Function Analysis

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091262

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